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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,938

Applicant(s)

CARLSON, THOMAS B.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5-13,15 and 17-20 is/are allowed.
- 6) ☒ Claim(s) 2-4,14,16,21 and 24-31 is/are rejected.
- 7) ☒ Claim(s) 22 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the specification is withdrawn, in light of the insertion of the ATCC Accession number in the indicated locations.
3. The objection to claims 1, 2, 5, 14, 15, 17, 20-22, and 31 is withdrawn, upon further consideration.
4. The rejections of claims 1, 2, 5-13, 15-20, and 23-31 under 35 U.S.C. 112, 2nd paragraph, are withdrawn, in light of the claim amendments.
5. The rejection of claims 1-31 under 35 U.S.C. 112, 1st paragraph, for requiring a deposit of seed of corn variety, I015036, is withdrawn, in light of the deposit statement in the papers submitted 23 December 2002 and in the specification on page 29.

Claim Objections

6. Claims 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

7. Claims 3, 4, 14, 21 remain and claims 2, 16, 27, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 18 September 2002 under item 3. Applicant traverses the rejections in the paper received 23 December 2002. Applicant's arguments have been fully considered but were not found persuasive.

Regarding the rejection of claims 3 and 4, Applicant argues that it is not necessary that the population of claim 2 be an essentially homogenous population of seed, and that the population of claim 2 may potentially include a small amount of other seed, yet still comprise a population of seed of corn variety I015036 (response, page 5, 4th and 5th paragraphs). However, there is no indication in claim 2 that the population can comprise other seed. Claim 2 is not directed to a population of seed comprising seed of corn variety I015036 and other seed types. It is drawn to a population of seed of the corn variety of I015036. There is nothing to indicate that any other seed variety is in the population.

Regarding the rejection of claim 14, Applicant argues that while it is true that I015036 seed can only produce I015036 plants, it is not required that a population of plants produced by growing I015036 seeds only contains I015036 plants. To explain this statement, Applicant suggests an example in which a collection of I015036 seed used to plant the population of I015036 plants may contain small amounts of other kinds of seed. Or alternatively, other types of plants, such as weeds, may grow within a population of plants that are grown (response, page

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6, 2nd full paragraph). However, the claim clearly states that the population of corn plants is produced by growing seed of the corn variety of I015036, not a contaminated collection of I015036 seed. The claim makes no mention of any other seed. Therefore, the only plant that can be in a population of plants grown from seed I015036 is an I015036 plant. It does not matter that some other plant may grow next to a I015036 plant, as the other plant was not produced by I015036 seed.

Regarding claim 21: Applicant argues that the specification defines "crossing" as "The pollination of a female flower of a corn plant, thereby resulting in the production of seed from the flower", and that in light of this definition that it is clear that crossing in claim 21 is done one time. Applicant argues that claim 21 specifies that "seed is allowed to form", and that if multiple generations were involved the claim would have to specify that after the seed is formed, it is planted and crossing takes place again (response, paragraph bridging pages 6-7). However, the term "comprising" in line 1 of claim 21 indicates that the claimed process may contain more than just the stated step. Further, dependent claim 22 further defines the process of claim 21 as a process of producing F1 hybrid corn seed, which also indicates that the process of claim 21 can involve other steps. As Applicant admittedly intends for the seed produced by claim 21 to be an F1 generation, it is again suggested that the claim be amended by inserting --F1-- in line 1 before "corn seed", so that the claim clearly indicates this.

In claim 2: the recitation "population of seed of the corn variety I015036" renders the claim indefinite, because it is not clear if the population only consists of I015036 seed or if it also comprises other seed. The specification at page 6 indicates that a population of inbred seed can further be defined as being essentially free from hybrid seed (lines 8-11, emphasis added).

However, the specification does not provide a definition for "population" itself. Claim 2 indicates that the population is of only I015036 seed, there is not mention of any other seed types or plants. It is not clear if the population of claim 2 consists only of I015036 seed, or if it also comprises other types of seed.

In claims 16 and 27: the claims broaden the scope of the claims from which they depend. The claims add on a gene and trait to the plant of their parent claims. There is no indication as to how the plants acquired the genes, and the gene is not possessed by the plant of their parent claims.

8. Claims 3, 14, and 24-31 remain and claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 18 September 2002 under item 4. Applicant traverses the rejection in the paper filed 23 December 2002. Applicant's arguments were fully considered but were not found persuasive.

In response to the aspect of the rejection concerning the description of non-I015036 seeds in an essentially homogenous population of I015036 seeds, Applicants argue that they note that the Office has issued more than 75 patents including claims to populations of corn seed of a given variety, and that the impetus of the instant rejection is therefore not understood. Applicants also argue that the identity of other seed included in a population of I015036 seed is irrelevant, that the fact that the population may be contaminated with other seed hardly takes the

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claim out of compliance with written description (response, page 7, 3rd full paragraph and the paragraph bridging pages 7-8). However, the allowability of claims in any given patent application is decided based on the fact patterns present within that application, not on the fact patterns of other applications. Further, contrary to what Applicant believes, the other members of an "essentially homogeneous population" need to be described, as all members of the population are encompassed by the claim. One would not use the "contaminants" or other plants in the same way as plants of line I015036. If a composition contains an ingredient that is not described, then how can the composition be described?

Regarding other issues raised in the rejection, Applicant argues that the specification provides a detailed description of hybrid 8012681, which was produced with I015036 as one inbred parent, and that the description of this hybrid along with the fact that any hybrid derived from I015036 will contain half of its genes is more than adequate to provide a description of hybrid plants and seeds (response, page 8, 1st full paragraph). Applicants cite *The Regents of The University of California v. Eli Lilly* and argue that all of the members of the claimed genus of hybrids having I015036 as one parent share the identical structural feature of having the genetic complement of I015036 (paragraph bridging pages 8-9). However, hybrid 8012681 is just one species of the rather broad genus of all hybrid plants and seeds that can be produced by crossing I015036 to any other corn plant. The morphological and physiological traits of 8012681 are not representative of all of the hybrids encompassed by the claims. That any hybrid plant will inherit half of its genes from I015036 does not provide sufficient information of how those genes or its products will be affected by or interact with the genes and their products inherited from the other parent. The fact that any hybrid plant will inherit half of its genes from I015036 then does not

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provide sufficient information of the morphological and physiological characteristics expressed by that hybrid plant. The specification does not correlate the morphological and physiological traits of 8012681 with the structure of its genes that it inherited from I015036. Most of the traits of I015036 described in the specification are not governed by a single gene, and so the knowledge that the claimed hybrids have inherited half of its genes from I015036 does not provide any information concerning the morphological and physiological traits of the hybrids. One cannot describe all of the morphological and physiological characteristics of corn plant 8012681 that also definitely will be expressed by other hybrids, nor can one describe the characteristics that will be different. Further, all of the hybrids having I015036 as one parent must also have inherited half of its genes from the other parent. However, descriptions of the other parents are lacking. The other parent of only a single species of the broad genus of hybrids encompassed by the claims is described, which is the other parent for 8012681 (specification, page 53, lines 17-20).

Applicants argue that the specification provides an SSR genetic marker profile of I015036 in Table 6, and that because plant I015036 is an inbred all hybrid plants will have these same SSR genetic markers and thus will be genetically distinct and identifiable from any other corn plant. (response, paragraph bridging pages 8-9 and page 9, 1st full paragraph). However, the presence of these SSR markers does not describe the morphological and physiological traits expressed by the hybrids. None of these markers have been linked to any expressed traits. The structures of these markers have not been correlated with any expressed traits. Further, Table 6 shows that at least two other corn plants share many of the same loci, and so these shared loci do not distinguish the claimed plants from other plants. It is also noted that the specification does

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not describe the sequences of the primers that were used to produce this SSR profile, nor the PCR conditions one would need to conduct the experiments. The specification indicates, at the bottom of Table 6, that the primers are from Celera Amgen. However, the sequences of the primers are not described, and it is not clear if these primers are freely available to the public, and if they would remain so for the term of a patent should one issue from the instant application. Further, without a description of the sequences of the SSR, one cannot confirm that the same SSR has been detected.

Applicant also argues, concerning the claimed plants further comprising single locus conversions and transgenes, that they have more than adequately described plants that comprise essentially all of the desired morphological and physiological characteristics of I015036 by way of descriptions of I015036 (response, paragraph bridging pages 9-10 and page 10, 1st full paragraph). However, the claims broadly encompass the introduction of genes that have not been discovered or isolated. Such genes are clearly not described by the specification. Further, the description of I015036 does not describe the morphological and physiological characteristics of the claimed plants, as the impact that the single locus or transgene has on the plant depends on the product it encodes, and its interaction with other plant products, among other considerations. It is incorrect to generally and simply conclude that a plant having just one extra gene would still essentially have all of the morphological and physiological traits as the same plant without that gene. Applicants also argue that the rejection ignores the methodology for creating single locus conversions and transgenic corn plants, and that single locus traits for conferring male sterility, waxy starch, herbicide resistance, etc. are described (response, page 10, 2nd full paragraph to the paragraph bridging pages 11-12). However, a method of producing a product does not describe

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the product itself. Applicants argue that they do not have to describe every possible single locus conversion (response, page 12, 1st full paragraph). However, the specification cannot describe genes that have not been discovered. Applicant argues that the specification provides an adequate description of single locus conversion. But the specification does not provide the source where one may obtain all of the genes that are listed in the specification. For example, Applicant's response indicates that the specification describes the single locus that confers "yield stability"(response, page 10, 2nd full paragraph). While the specification includes this in a list of single loci, it does not provide the sequences of the loci itself, or an indication that the prior art teaches that they have been isolated at the time the instant invention was filed. For example, a single locus that confers yield stability is not known. It is suggested that the claims drawn towards plants comprising single locus conversions be amended to recite the types of single genes that confer traits contemplated in the specification, for example genes conferring viral resistance, or male sterility, provided the prior art teaches that those types of genes have been isolated and therefore reduced to practice.

9. Claims 27, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a corn plant produced by growing seed of I015036, further defined as having a genome comprising a single locus conversion.

The specification teaches that single locus conversions of the disclosed corn plant refers to plants that are developed through backcrosses wherein essentially all of the desired morphological and physiological characteristics of the inbred are recovered in addition to a single locus transferred by the backcrossing technique (page 29, lines 20-24). However, the specification does not teach any I015036 plants comprising single locus conversions produced by a single cross. The specification at pages 35-36 provides an example of a DEKALB proprietary inbred corn plant that was single locus converted. The example summarizes the crosses performed. However, this example leaves out information, such as the number of crosses that were performed at each step. For example, page 35, line 12 recites "backcrossed times 85DGD1". The direction provided in the example is not complete.

It is not clear that single loci may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant.

Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created

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in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

Claim Rejections - 35 USC § 102 & 103

10. Claims 24, 25, and 26 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Getschman (U.S. Patent No. 6,043,417), for the reasons of record stated in the Office action mailed 18 September 2002 under item 6.

Applicant traverses the rejection in the paper filed 23 December 2002. Applicant's arguments were fully considered but were not found persuasive.

The rejection is withdrawn from claims 1-5, 7-10, 12-23, and 27-31, as plant I015036 expresses morphological and physiological traits that distinguish it from the plants taught by the reference.

Applicant argues that the Office has the burden of showing that each and every element as set forth in the claims is found in the prior art, and must be shown as in complete detail as contained in the claim (response, page 13, 4th full paragraph). First, it is noted that claims 24-26 set forth any morphological and physiological characteristics of the claimed hybrid plants

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produced by the claimed hybrid seeds. Prior art plants and seeds therefore cannot be distinguished from the claimed plants and seeds based on this criterion. The claims indicate that the hybrid seed is produced by crossing plant I015036 with any another inbred corn plant.

Claims 24-26 are product-by-process claims, and may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Thorpe*, 227 USPQ 964,966 (Fed. Cir. 1985).

Claims 24-26 do not place any limitations on the morphological and physiological characteristics that the hybrid plants, produced from the hybrid seed, may express. Prior art plants and seeds having the same characteristics as the instantly claimed plants and seeds would anticipate the claimed products even if made by a different method (i.e., with different parent plants). Here, the instant claims do not place any limitation on the properties of the claimed plants and seeds themselves, and it is unknown if the properties differ from that of the plants and seeds taught by the reference. The plants and seeds taught by Getschman anticipate the instantly claimed plants and seeds, as their properties do not distinguish each other. As the claims do not place any phenotypic restrictions on the claimed products, the Examiner does not have sufficient facts to determine whether the progeny plants and seeds are inherently the same. The Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ from teachings of the reference, keeping in mind that it is the claimed products, not the process by which they are made, that must differ. Where the prior art product seems to be identical, except that the prior art is silent as to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 UPSQ 430, 433 (CCPA 1977).

Applicant argues that, to the extent alleged unexpressed inherent characteristics from the basis of an anticipation rejection, that these characteristics must flow from the disclosure, and the silence of a reference to an asserted silent characteristic must be filled with recourse to extrinsic evidence (response, paragraph bridging pages 13-14). However, as discussed above, the Examiner does not have sufficient facts to determine whether the claimed hybrid plants and the hybrid plants taught in the reference are the same. The claims do not recite any unique, identifying, or otherwise limiting characteristics of the plants and seeds that distinguish them from hybrid plants and seeds of the prior art. The burden shifts to Applicant to provide the evidence.

Applicant also argues that in order to establish a prima facie case of obviousness, that there must be motivation or suggestion to combine references in the cited prior art, a reasonable expectation of success, and the prior art must teach all of the claim limitations (response, paragraph bridging pages 14-15). Applicant argues that there is no motivation or suggestion to arrive at the invention, no motivation alleged in the Office action, and the rejection therefore relies on an "obvious to try" rationale. However, Getschman et al. teach hybrid corn plants and seeds. The rejection cites only one reference, and that reference teaches the claimed products. Applicants argue that there is no reasonable expectation of success that a second corn plant could be used to produce plants within the scope of the invention, and that the Office action has not shown that the prior art teaches or suggests all of the claim limitations. However, as discussed, the claims are utterly silent as to the morphological and physiological traits expressed by the claimed plants.

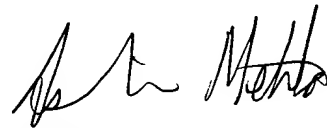
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11. Claims 1, 5-13, 15, and 17-20 are allowed. Claims 22 and 23 are objected to for being dependent upon a rejected base claim. Claims 2-4, 14, 16, 21, and 24-31 remain rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

April 4, 2003


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER